To: frank.von_arx@novartis.com[frank.von_arx@novartis.com]
Cc: marieeve.ebelin@novartis.com[marieeve.ebelin@novartis.com]; ivan.csendes@novartis.com[ivan.csendes@novartis.com]
Subject: RE: Studies linking drug-eluting stents to increased mortality/MI spark impassioned pleas for reason and calls for calm
Sent: Wed 9/13/2006 5:07:37 PM
From: Simhambhatla, Murthy (SC)

Dear Frank,

We don't see this discussion going away any time soon, even though these studies have not yet been published and we haven't seen the details. For this reason, we are in the process of dveloping a formal ABT position statement ahead of the TCT. I will contact you just as soon as we formalize this.

Our view is that Xience, a 2nd generation DES is safe and efficiacious as demonstrated by the SPIRIT II clinical data. Our design paradigm with thin struts, biocompatible polymers, and good coating integrity, together with very compelling pre-clinical results related to inflammation and thrombus burden relative to metallic stents bode well for this system as we continue to gather clinical data on Xience V.

Regards,
Murthy

From: frank.von_arx@novartis.com [mailto:frank.von_arx@novartis.com]
Sent: Wednesday, September 13, 2006 7:57 AM
To: Simhambhatla, Murthy (SC)
Cc: marieeve.ebelin@novartis.com; ivan.csendes@novartis.com
Subject: Studies linking drug-eluting stents to increased mortality/MI spark impassioned pleas for reason and calls for calm

Dear Murthy,

what is Abbott's position on this. We get a lot of questions currently from our management. Can you provide an assessment how this will impact on coated stents?

Thanks for your help

with kind regards,

Frank von Arx, DVM
Novartis Pharma AG
BU Infectious Diseases, Transplantation & Immunology
Head of Project Management TX & I
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Email : frank.von_arx@novartis.com

----- Forwarded by Frank von Arx/PH/Novartis on 13.09.2006 16:55 -----

Ivan Csendes

05.09.2006 08:41

To: David Cohen/PH/Novartis@PH, Margaret Prescott/PH/Novartis@PH, SABINE PFEFFER/PH/Novartis@PH, Frank von Arx/PH/Novartis@PH, Marie-Eve Ebelin/PH/Novartis@PH, Anthony Rosenberg/PH/Novartis@PH, Thomas Schmitz/PH/Novartis@PH, cdmaier@fischermegert.ch

cc:

Subject: Studies linking drug-eluting stents to increased mortality/MI spark impassioned pleas for reason and calls for calm

Category:

FYI

Studies linking drug-eluting stents to increased mortality/MI spark impassioned pleas for reason and calls for calm

September 3, 2006

WCC news

Barcelona, Spain - Many attendees of the **World Congress of Cardiology 2006** had quit the conference center for sunshine and sangria by the time **Drs Edoardo Camenzind** (University Hospital Geneva, Switzerland) and **Alain J Nordmann** (University Hospital Basel, Switzerland) took the stage Sunday evening with the final presentation of the hotline session, stunning the remaining audience members with evidence of increased death in patients randomized to drug-

eluting stents (DES) within the trial programs that secured approval for the devices in the first place.

Both of the meta-analyses combined all of the Cordis/J&J-sponsored Cypher randomized trials, as well as the Boston Scientific-sponsored Taxus program: one found an increased incidence of death and Q-wave MI with the Cypher stent and a trend toward increased death/Q-wave-MI with the Taxus, while the second found no differences in cardiac mortality but an increase in noncardiac mortality, again with the Cypher stent.

Dr Edoardo Camenzind

The separate presentations, which shared a single hotline slot—necessitating rushed synopses on the part of the presenters—spurred discussant **Dr Salim Yusuf** (McMaster University, Hamilton, ON) to deliver a thundering indictment of what he later described to the press as an "epidemic of madness" over misuse of PCI for stable angina in general and drug-eluting stents specifically.

"As clinicians we seem to have lost our clinical judgment, let alone our ability to view data and evidence," Yusuf stated. "We therefore need a thoughtful and selective approach to PCI, complementing full medical therapy. . . . The whole field of angioplasty has been led astray by a preoccupation with restenosis, for which study after study has shown has no prognostic value. We're chasing problems that are iatrogenic that naturally would not exist in people. We've had a perverse financial incentive on the practice of cardiology. It is time to stop and reevaluate."

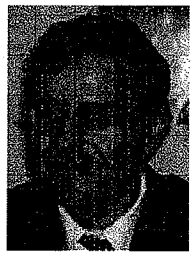
Two meta-analyses draw on company-sponsored trials

As clinicians we seem to have lost our clinical judgment, let alone our ability to view data and evidence.

Camenzind's meta-analysis was based on two separate analyses of the sirolimus and paclitaxel data. In the first, the investigators examined death and Q-wave MI in the published or presented papers, pooling them by time of follow-up. From eight to nine months of follow-up, out to one, two, and three years of follow-up, death/MI rates increased at rates that ranged from 30% to 40% higher in the Cypher-treated patients than those of the bare-metal-stent controls. A similar trend was seen, over time, for the paclitaxel-eluting stent, but here the relative difference between the Taxus and the bare-metal stent was only about 5% difference over the three years of follow-up.

In the second analysis, all of the randomized trials within each stent's program were stratified by last follow-up data. In this analysis, serious adverse events in sirolimus were 6.3% compared with 3.9% in the bare-metal-stent group (p=0.03) and in the paclitaxel trials were 2.6% vs 2.3% (p=NS).

"We conclude that death and Q-wave MI [as the] clinical presentation of stent thrombosis have a higher incidence in first-generation DES as compared with bare-metal controls," Camenzind stated. "Excess events appear to occur with both types of stents, although the magnitude seems to be higher with sirolimus. A risk/benefit analysis of systematic use of first-generation drug-eluting stents is warranted."



Dr Alain J Nordmann

Nordmann's findings, while raising the specter of increased deaths, actually clashed somewhat with those of Camenzind. Nordmann et al combined data from 17 randomized controlled trials of paclitaxel- or sirolimus-eluting stents to evaluate total mortality, cardiac mortality, and noncardiac mortality. While total mortality at one year trended toward a benefit of DES, at two, three, and four years the investigators saw a trend toward increased mortality with DES. For cardiac mortality, however, there was no statistically significant difference between DES and bare-metal stents or for either sirolimus- or paclitaxel-eluting stent compared with bare-metal

stents. Most striking, however, was the data for noncardiac deaths, which at two and three years pointed to an association between sirolimus stent implantation and increased noncardiac mortality. Separate analyses identified these deaths as cancer, stroke, or lung disease.

"DES for the treatment of coronary artery disease do not reduce mortality when compared with bare-metal stents," Nordmann concluded. "Preliminary evidence suggests that sirolimus but not paclitaxel may lead to an increase in noncardiac mortality. Long-term follow-up and assessment of cause-specific deaths in patients receiving DES are mandatory to determine safety of patients receiving these devices."

Impassioned calls for a fresh look at DES, without industry involvement

Dr Salim Yusuf

To the press, Nordmann pointed out that obtaining raw data on mortality from the stent manufacturers had been "extremely difficult," highlighting the need for non-company-sponsored, large randomized clinical trials with ample follow-up.

At the very least, said Yusuf, large registries should be mandated to track adverse events in DES recipients. But Yusuf also made a plea to the major cardiovascular organizations to step up and revisit not only the use of DES but the role of PCI in the treatment of stable, non-drug-refractory angina. And to be clear, he added, **PCI and drug-eluting stents play a key role in the treatment of unstable angina and acute coronary syndrome—it is as a treatment for stable angina to treat non-life-threatening restenosis that Yusuf singles out as a "myth" and a "man-made disease."**

Long-term follow-up and assessment of cause-specific deaths in patients receiving DES are mandatory to determine safety of patients receiving these devices.

As for the meta-analyses themselves, Yusuf stated: "These new studies raise concern. I do not believe these trials are convincing, but they are disconcerting given that we have no data that this procedure is useful. There is a significant excess in noncardiac deaths, and we need to find out if this is real."

Pausing to assure a tittering audience that he was dead serious in his comments, Yusuf added, "I call on the **ESC** to [convene] a balanced and independent working group, and not just of interventionalists. Certainly you can bring them in, but also noninterventionalists, health economists, patient representatives, and government representatives, and have a committee to find out what the real role of **PCI** is, of these stents, and keep industry out of it."

Camenzind, for his part, stopped short of denying a role for drug-eluting stents, insisting that his study, and his misgivings, apply only to the two first-generation drug-eluting stents. "We need stents that can control restenosis, that don't totally abolish the healing process but that are able to control it."

Third study also sparks debate

Yet another study, presented earlier in the day by **Dr Peter Wenaweser** (Thorax Center, Rotterdam, the Netherlands) also highlighted the stent thrombosis risk with DES. In the study, Wenaweser and colleagues examined rates of early and late stent thrombosis in patients enrolled in the **SIRTAX** and **Post-SIRTAX** registries in Bern and the **RESEARCH** and **T-SEARCH** registries in Rotterdam, between April 2002 and December 2005. In Bern, patients received clopidogrel and aspirin for three to six months, while in Rotterdam, patients received dual antiplatelet therapy for three to 12 months. Only angiographically documented stent thromboses were included in the analysis.

All of the presentations are pointing to the fact that stent thrombosis is there and needs a solution. It exists, but it's not terrifying.

In all, 152 stent thromboses occurred in 8146 patients. The cumulative incidence of stent thrombosis was 2.9%, yielding a rate of 1.3 per 100 patient-years. The rate of stent thrombosis was 1.2% at 30 days, 1.7 at one year, 2.3 at two years, and 2.9% at three years, "an almost linear increase of 0.6% per year between 30 days and three years," Wenaweser commented.

In interviews with **heart*wire***, experts tried to put the findings in perspective, offering the oft-repeated calls for longer clopidogrel duration. **Dr Antonio Colombo**'s group (Columbus Hospital, Milan, Italy) has a forthcoming paper examining rates of stent thrombosis in patients who quit dual antiplatelet therapy at one year, compared with patients who stayed on the drug out to three years.

Dr Peter Wenaweser

"I think all of the presentations are pointing to the fact that stent thrombosis is there and needs a solution," Colombo told **heart*wire***. "It exists, but it's not terrifying. My problem with this issue is that we did not use bare-metal stents in situations where we now use DES, so I doubt we can do a fair comparison of stent thrombosis between DES and bare-metal stents."

He also questions whether stent thrombosis rates continue to climb after two years. "I'm not convinced that we have a continuous rate, I think it probably grows up to two years, but from two years on, tends to level off. . . . We should not forget that so many patients in the randomized trials have been off antiplatelet therapy for a long time, and those patients are not dying and having MIs all the time."

Also commenting on the Wenaweser study for **heart*wire***, **Dr Anthony Gershlick** (Nuffield Leicester Hospital, UK) insisted that it is important to see published papers before jumping to conclusions. For one thing, Wenaweser did not present data on percentage follow-up, making it difficult to appreciate stent thrombosis rate increases over time. As well, there are no studies

tracking the "cumulative" stent thrombosis rate for bare-metal stents. "The absolute difference between DES and bare-metal stents will not be 2.9%, it will be 2.9% minus the cumulative rate for bare-metal stents," he noted. "What we need to know is the excess cumulative risk."

Abbott
A Promise for Life

News

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ABBOTT BEGINS EARLY INTERNATIONAL LAUNCH OF XIENCE™ V EVEROLIMUS ELUTING CORONARY STENT SYSTEM

– Company Expects to Achieve a Leadership Position in Drug-Eluting Stent Market with XIENCE V –

ABBOTT PARK, Ill. Oct. 3, 2006 – Abbott today announced that it has begun the international launch of the XIENCE™ V Everolimus Eluting Coronary Stent System for the treatment of coronary artery disease earlier than the company's original projections. The XIENCE V stent system will be launched in the majority of European countries immediately. The company also announced that it will focus its commercial, manufacturing and clinical resources on the successful launch of XIENCE V and will not pursue commercialization of its ZoMaxx™ Drug-Eluting Coronary Stent System.

"The positive, differentiating clinical results that XIENCE V demonstrated in SPIRIT II, combined with positive physician feedback about XIENCE V, indicates that XIENCE has significant potential to meet critical next-generation drug-eluting stent needs for physicians and patients," said John M. Capek, Ph.D., president, Cardiac Therapies, Abbott Vascular.

-more-

ABBOTT BEGINS EARLY INTERNATIONAL LAUNCH OF XIENCE™ V EVEROLIMUS ELUTING CORONARY STENT SYSTEM
PAGE 2

Positive clinical results for XIENCE V from the SPIRIT II trial announced at the World Congress of Cardiology on September 5, 2006, demonstrated that XIENCE V showed statistically significant superiority to the TAXUS® paclitaxel-eluting coronary stent system with respect to the study's primary endpoint, which was angiographic in-stent late loss at six months. Twelve-month results from SPIRIT II and nine-month results from SPIRIT III will be presented in the first half of 2007. The XIENCE V stent system has received CE Mark and is currently an investigational device in the United States and Japan.

"The XIENCE V drug-eluting stent system offers an excellent combination of technologies to deliver an advanced treatment for patients with coronary artery disease," said Eulogio Garcia Fernandez, M.D., Gregorio Marañón University General Hospital, Madrid, Spain. "Its highly deliverable MULTI-LINK VISION® coronary stent platform, the biocompatible coating and the anti-proliferative, anti-inflammatory, everolimus, plus encouraging clinical results, suggest that XIENCE V will become a preferred treatment of choice for coronary artery disease in Europe."

Focus on XIENCE V

After analyzing the clinical data from both the XIENCE V and ZoMaxx programs, Abbott has determined that it will not pursue commercialization of ZoMaxx, and will instead focus its commercial, manufacturing and clinical resources on XIENCE V. Nine-month clinical data from ZOMAXX I, Abbott's international ZoMaxx trial, will be presented at the Transcatheter Cardiovascular Therapeutics (TCT) meeting in Washington D.C. on October 23, 2006.

-more-

ABBOTT BEGINS EARLY INTERNATIONAL LAUNCH OF XIENCE™ V EVEROLIMUS ELUTING CORONARY STENT SYSTEM
PAGE 3

"We have conducted a thorough analysis of all available clinical data for both XIENCE V and ZoMaxx, and have concluded that XIENCE V is a significantly better product," said Richard A. Gonzalez, president and chief operating officer, Abbott. "Following encouraging physician feedback from our pre-launch evaluation program in Europe, and given the positive XIENCE V data, we remain confident in our ability to achieve a leadership position in the drug-eluting stent market with the XIENCE V platform."

Abbott recently announced that it is expanding its drug-eluting stent manufacturing capacity in Ireland to prepare for future launches in the U.S. and Japan.

"Abbott is pleased to offer XIENCE V as a new treatment option to European physicians for patients with coronary artery disease, which remains a leading cause of death around the world," Capek said. "As a leader in vascular care, Abbott will continue to deliver on its commitment to provide innovative technologies to advance the treatment of vascular disease."

SPIRIT V Clinical Trial

Abbott also announced it will initiate SPIRIT V, an international study that will provide additional clinical experience with the XIENCE V stent system in approximately 3,000 patients at approximately 100 sites throughout Europe, Asia, Canada and Latin America. The trial consists of two concurrent studies, the Diabetic Study and a Registry. The SPIRIT V Diabetic Study is a prospective, randomized, single-blind study comparing the XIENCE V stent system to the TAXUS® Liberté™ stent system in the treatment of diabetic patients with coronary artery lesions who will fulfill the eligibility criteria. The SPIRIT V Registry is a prospective, single-arm, registry evaluating performance of the XIENCE V stent system in real-world clinical settings.

-more-

ABBOTT BEGINS EARLY INTERNATIONAL LAUNCH OF XIENCE™ V EVEROLIMUS ELUTING CORONARY STENT SYSTEM
PAGE 4

About the SPIRIT Family of Trials

The SPIRIT FIRST study of the XIENCE V Stent System showed positive results through two years with no MACE events between one and two years in patients with *de novo* native coronary artery lesions. SPIRIT II and SPIRIT III are large-scale pivotal clinical trials comparing XIENCE V to the TAXUS paclitaxel eluting coronary stent system. SPIRIT IV, which already has more than 100 patients enrolled, will evaluate the safety and efficacy of the XIENCE V Stent System for the treatment of coronary artery disease in a more complex patient population in the United States.

About Abbott Vascular

Abbott Vascular, a division of Abbott, is one of the world's leading vascular care businesses. Abbott Vascular is uniquely focused on advancing the treatment of vascular disease and improving patient care by combining the latest medical device innovations with world-class pharmaceuticals, investing in research and development, and advancing medicine through training and education. Headquartered in Northern California, Abbott Vascular offers a comprehensive portfolio of vessel closure, endovascular and coronary products that are recognized internationally for their safety, effectiveness and ease of use in treating patients with vascular disease.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs 65,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's Web site at www.abbott.com.

###

Information contained herein for presentation to healthcare professionals outside the United States and Japan only.

SPIRIT III data contained herein were presented by Dr. Gregg Stone at the Late Breaking Clinical Trials Session in the i2 Summit at ACC on March 24, 2007.

Abbott Vascular

Clinical, Angiographic, and IVUS Results from the Pivotal U.S. Randomized SPIRIT III Trial of the XIENCE V Everolimus Eluting Coronary Stent System

Gregg W. Stone, MD
for the SPIRIT III Investigators

[redacted]

AP2925547A

Disclosures

- **Gregg W. Stone MD**
  - **Consultant to and speaker honoraria from Abbott Vascular and Boston Scientific**

[redacted]

AP2925547A

Highly Confidential

Background

The XIENCE V DES elutes everolimus from a thin (7.8 μm), robust, durable biocompatible fluoropolymer, incorporating thin cobalt chromium stent struts (0.0032") for enhanced flexibility and deliverability.

The 300 pt randomized SPIRIT II trial found that the XIENCE V stent compared to the TAXUS® stent reduced angiographic late loss at 6 months (0.11 ± 0.27 mm vs. 0.36 ± 0.39 mm, P<0.0001).

The SPIRIT III trial was thus designed as the U.S. pivotal approval study for the XIENCE V stent.

[redacted]

AP2925547A

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A1319

ABT1098587

Cordis et al. v. Abbott et al.
C.A. Nos. 07-2265, -2477, -2728, -5636 (D. N.J.)

Study Algorithm

1002 pts enrolled at 65 U.S sites

RVD ≥ 2.5 mm - ≤ 3.75 mm; Lesion length ≤ 28 mm

Max. 2 lesions each in a different epicardial vessel

Pre-rand: ASA ≥ 300 mg, clopidogrel ≥ 300 mg load unless on chronic Rx

Randomized 2:1 XIENCE V:TAXUS®

Stratified by diabetes and intent for 1 vs. 2 lesion treatment

Pre-dilatation mandatory

Everolimus Eluting	Paclitaxel-eluting
XIENCE V	**TAXUS®**

Aspirin ≥ 80 mg QD for 5 years; Clopidogrel 75mg QD for ≥ 6 months

Clinical f/u: 1, 6, 9 months and yearly for 1-5 years

Angio f/u (N=564) @ 8 mos; IVUS f/u (N=240) @ 8 mos

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SPIRIT III Endpoints

- **Primary Endpoint:** In-segment late loss (LL) at 8 months
  - Assume LL = 0.24 ± 0.47 mm in both arms
  - Non-inferiority margin = 0.195 mm, one-sided α = 0.025
  - 564 total pts ⇒ 99% power (assuming 10% dropout)
  - Pre-specified sequential non-inferiority and superiority tests
  - In pts with 2 lesions, primary endpoint analysis based on a randomly assigned "analysis lesion"
- **Major Secondary Endpoint:** Ischemia-driven target vessel failure (TVF) at 9 months
  - Assume TVF rate = 9.4% in both arms
  - Non-inferiority margin = 5.5%, one-sided α = 0.05
  - 1,002 total pts ⇒ 89% power (assuming 1% dropout)
  - **Both 1° and major 2° endpoints must be met for success**

[redacted]

AP2925547A

Clinical Trial Organization

• **Principal Investigator:**	**Gregg W. Stone, MD** Columbia University Medical Center, NY
• **Principal Investigator: Japanese Arm:**	**Shigeru Saito, MD** Shonan Kamakura Hospital, Japan
• **Angiographic Core Lab:**	**Alexandra Lansky, MD** CRF, NY
• **IVUS Core Lab:**	**Peter Fitzgerald, MD, PhD** Center for Research in CV Intervention, CA
• **CEC:**	**Kenneth Mahaffey, MD** Duke Clinical Research Institute, NC
• **DSMB:**	**David Faxon, MD** Center for Advanced Medicine, IL
• **Randomization Service:**	**ICON Clinical Research,** Sugarland, TX
• **PK Core Lab:**	**CRL Medinet B.V.,** The Netherlands

[redacted]

AP2925547A

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A1322

ABT1098590

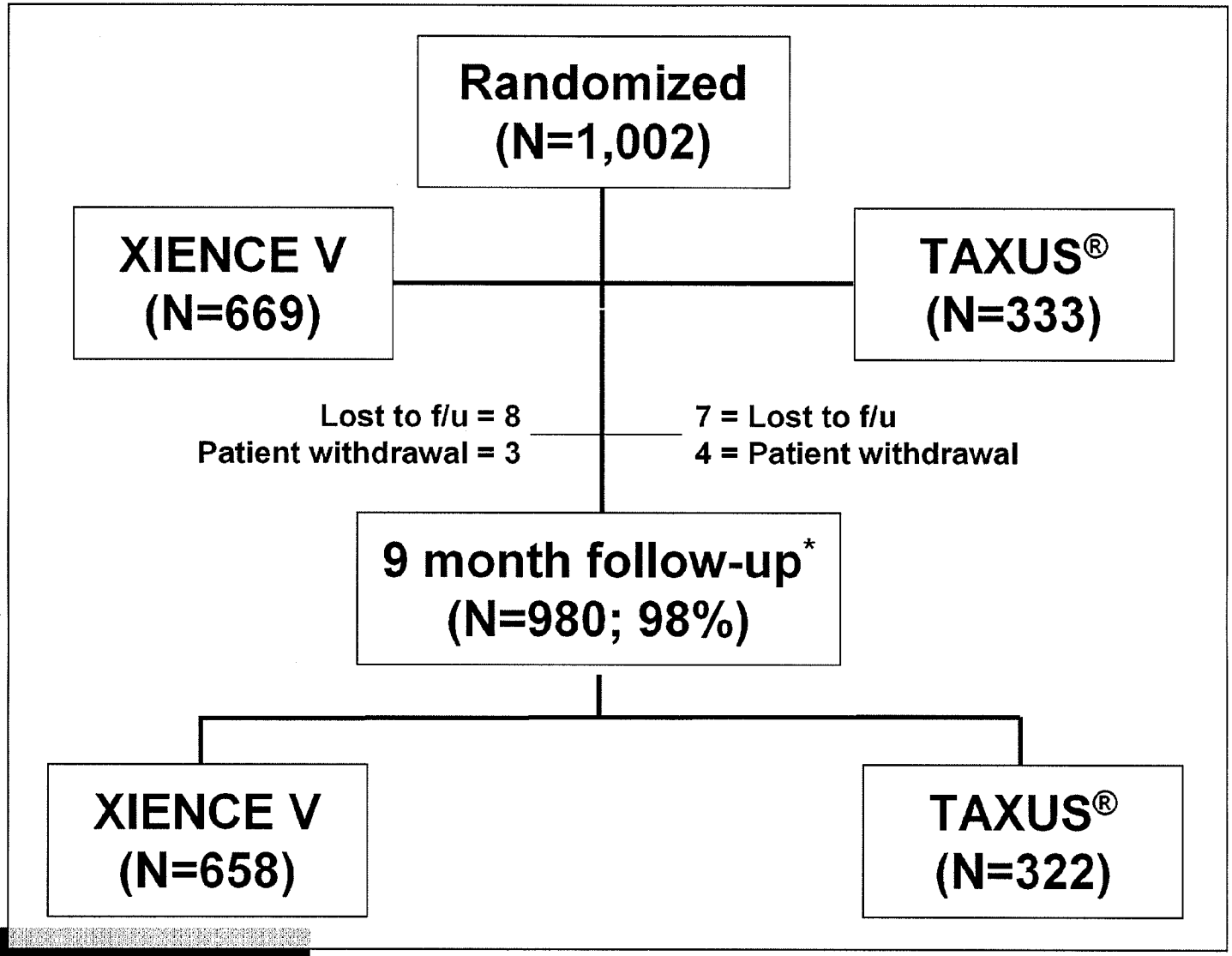
Cordis et al. v. Abbott et al.
C.A. Nos. 07-2265, -2477, -2728, -5636 (D. N.J.)

Top 20 Enrollers

	Patients		Patients
M. Midei St. Joseph Medical Center, Towson, MD	107	**J. Young** The Christ Hospital, Cincinnati, OH	27
W. Newman Wake Medical Center, Raleigh, NC	90	**A. Carter** Borgess Medical Center, Kalamazoo, MI	24
M. Sanz St. Patrick Hospital, Missoula, MT	60	**D. Williams** Rhode Island Hospital, Providence, RI	23
J. Hermiller The Heart Center of IN, Indianapolis, IN	48	**R. Fortuna** Scripps Memorial Hospital, La Jolla, CA	20
J. Williams Presbyterian Hospital, Charlotte, NC	41	**M. Collins** Columbia Univ. Med. Ctr., New York, NY	19
N. Farhat EMH Regional Medical Center, Elyria, OH	39	**L. Mauri** Brigham & Women's Hospital, Boston, MA	18
R. Caputo St. Joseph's Hospital, Syracuse, NY	32	**L. Cannon** Northern Michigan Hospital, Petoskey, MI	18
N. Xenopoulos Jewish Hospital, Louisville, KY	29	**R. Matthews** Good Samaritan Hosp., Los Angeles, CA	16
R. Applegate N. Carolina Baptist Hosp., NC	29	**H. Dauerman** Fletcher Allen Healthcare, Burlington, VT	16
P. Gordon The Miriam Hospital, Providence, RI	29	**D. Netz** Nebraska Heart Hospital, Lincoln, NE	14

AP2925547A

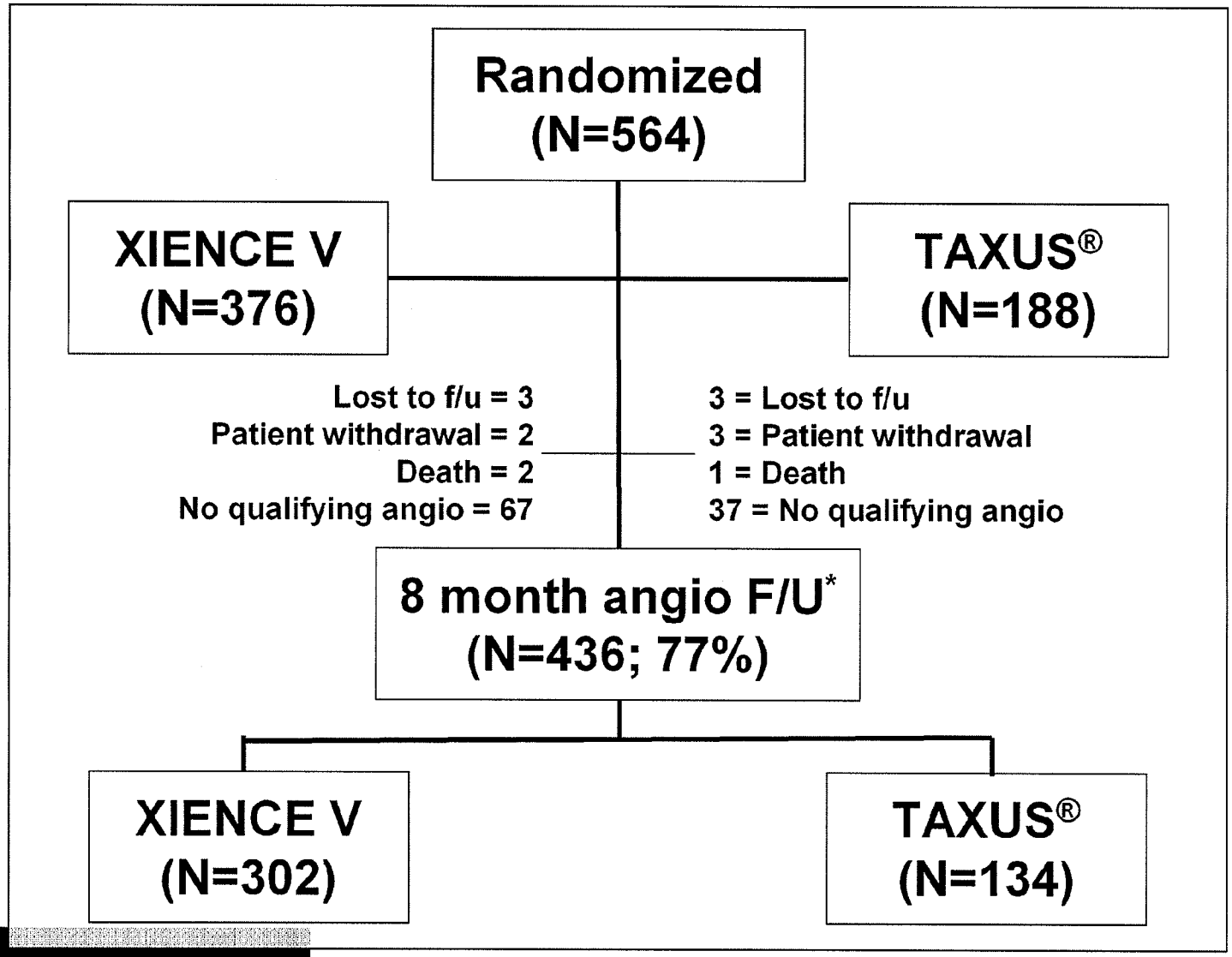
Patient Flow - Clinical



[redacted]

AP2925547A

Patient Flow - Angiographic



[redacted]

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Baseline Demographics

	XIENCE V 669 pts	TAXUS 333 pts	P value
Age (in years)	63.2 ± 10.5	62.8 ± 10.2	0.54
Male (%)	70.1	65.7	0.17
Hypertension (%)	76.2	74.0	0.48
Hypercholesterolemia (%)	74.2	71.5	0.36
Diabetes mellitus (%)	29.6	27.9	0.60
Insulin requiring (%)	7.8	5.5	0.19
Current smoker (%)	23.4	22.5	0.81
Prior MI (%)	19.9	18.0	0.49
Unstable angina (%)	18.7	25.1	0.02

[redacted]

AP2925547A

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ABT1098594

Cordis et al. v. Abbott et al.
C.A. Nos. 07-2265, -2477, -2728, -5636 (D. N.J.)

A1326

Baseline Angiography

	XIENCE V 767 lesions	TAXUS 382 lesions	P value
Lesion location			
LAD	41.3%	42.9%	0.61
LCX	27.6%	28.3%	0.83
RCA	31.0%	28.5%	0.41
LMCA	0.1%	0.3%	0.55
QCA			
RVD (mm)	2.77 ± 0.45	2.76 ± 0.46	0.87
MLD (mm)	0.82 ± 0.41	0.83 ± 0.40	0.79
% DS	70.0 ±13.3	69.4 ±13.6	0.54
Lsn length (mm)	14.7 ± 5.6	14.7 ± 5.7	0.92

[redacted]

AP2925547A

Procedural Results

	XIENCE V 669 pts 768 lesions	TAXUS 332 pts 382 lesions	P value
# lesions/pt*	1.2 ± 0.4	1.2 ± 0.4	1.0
2 lesion pts*	15.4%	15.4%	1.0
# stents/pt†	1.3 ± 0.6	1.3 ± 0.5	0.27
# stents/lesion†	1.2 ± 0.4	1.1 ± 0.3	0.07
Max. stent diameter/lesion (mm)	3.0 ± 0.4	3.0 ± 0.4	1.0
Max. stent diameter/RVD	1.1 ± 0.1	1.1 ± 0.1	0.56
Total stent length/lesion	22.8 ± 8.4	21.6 ± 7.8	0.02
Total stent length/lesion length	1.6 ± 0.5	1.5 ± 0.5	0.01
GPIIb/IIIa usage/pt	27.5%	24.7%	0.36

[redacted]xcept 5 pts in whom a single vessel had two lesions
8 were non study stents

AP2925547A

Post Procedure QCA

	XIENCE V 766 lesions	TAXUS 379 lesions	P value
RVD (mm)	2.84 ± 0.45	2.84 ± 0.46	0.74
Acute gain (mm)			
In-segment	1.54 ± 0.51	1.53 ± 0.50	0.62
In-stent	1.89 ± 0.48	1.91 ± 0.47	0.56
MLD (mm)			
In-segment	2.37 ± 0.45	2.36 ± 0.45	0.73
In-stent	2.71 ± 0.43	2.74 ± 0.41	0.38
% DS			
In-segment	13.5 ±7.6	14.4 ± 7.1	0.06
In-stent	0.3 ± 8.9	-0.2 ± 9.9	0.37

[redacted]

AP2925547A

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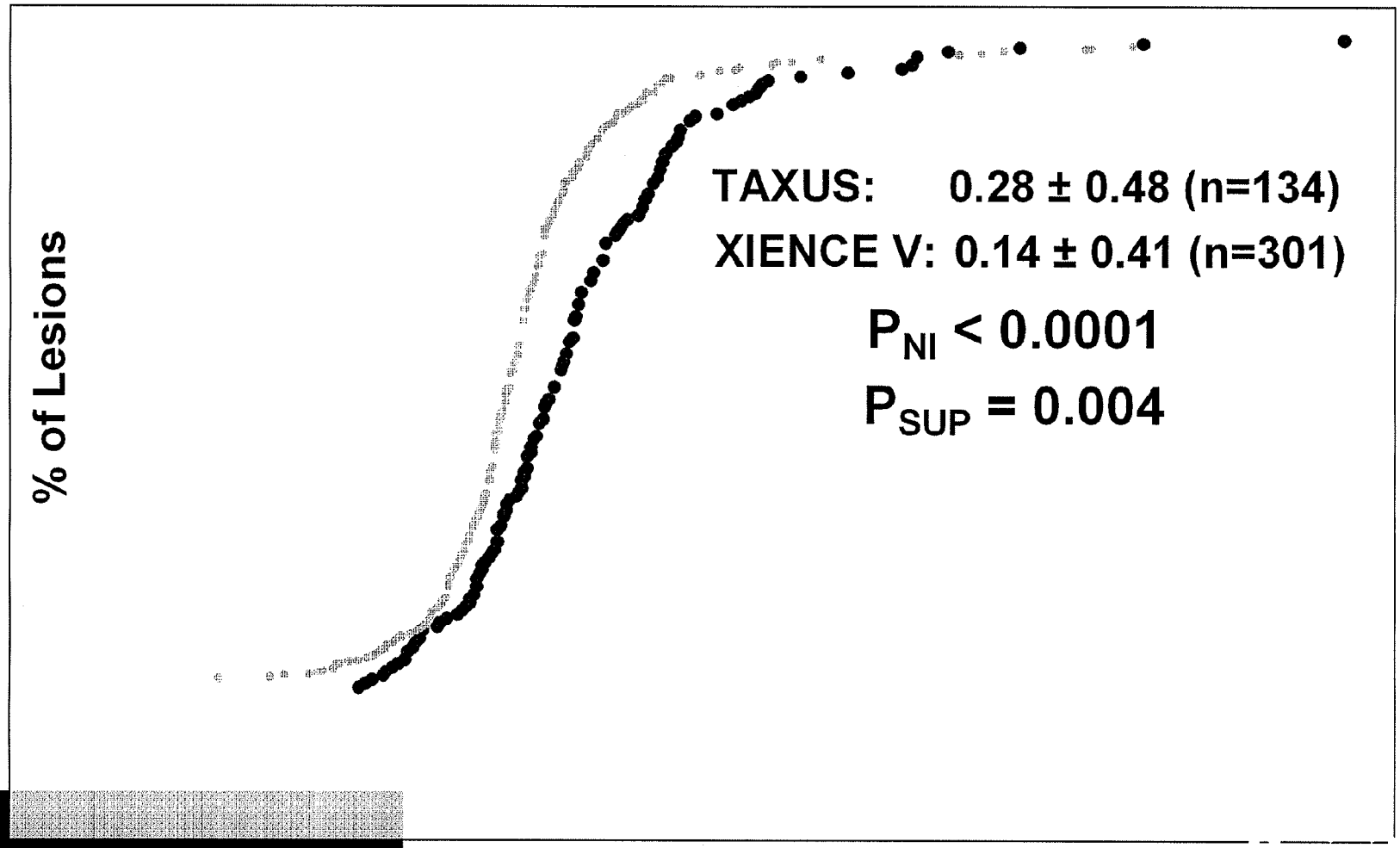
A1329

ABT1098597

Cordis et al. v. Abbott et al.
C.A. Nos. 07-2265, -2477, -2728, -5636 (D. N.J.)

Primary Endpoint: In-segment LL at 8 Months*
(Analysis Lesion)



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Late Loss at 8 Months*

	XIENCE V 301 patients	TAXUS 134 patients	P value
Analysis lesion	**301 lesions**	**134 lesions**	
In-segment	0.14 ± 0.41	0.28 ± 0.48	0.004
In-stent	0.16 ± 0.41	0.31 ± 0.55	0.006
All lesions	**343 lesions**	**158 lesions**	
In-segment	0.14 ± 0.39	0.26 ± 0.46	0.003
In-stent	0.16 ± 0.41	0.30 ± 0.53	0.002

[redacted]

AP2925547A

Highly Confidential

A1331

ABT1098599

Cordis et al. v. Abbott et al.
C.A. Nos. 07-2265, -2477, -2728, -5636 (D. N.J.)

QCA at 8 Months*
(All Lesions)

	XIENCE V 344 lesions	TAXUS 158 lesions	P value
RVD (mm)	2.77 ± 0.43	2.78 ± 0.42	0.84
MLD (mm)			
In-segment	2.22 ± 0.53	2.12 ± 0.60	0.08
In-stent	2.56 ± 0.53	2.45 ± 0.65	0.07
% DS			
In-segment	18.8 ± 14.4	22.8 ± 16.4	0.008
In-stent	5.9 ± 16.4	10.3 ± 21.4	0.02

[redacted]

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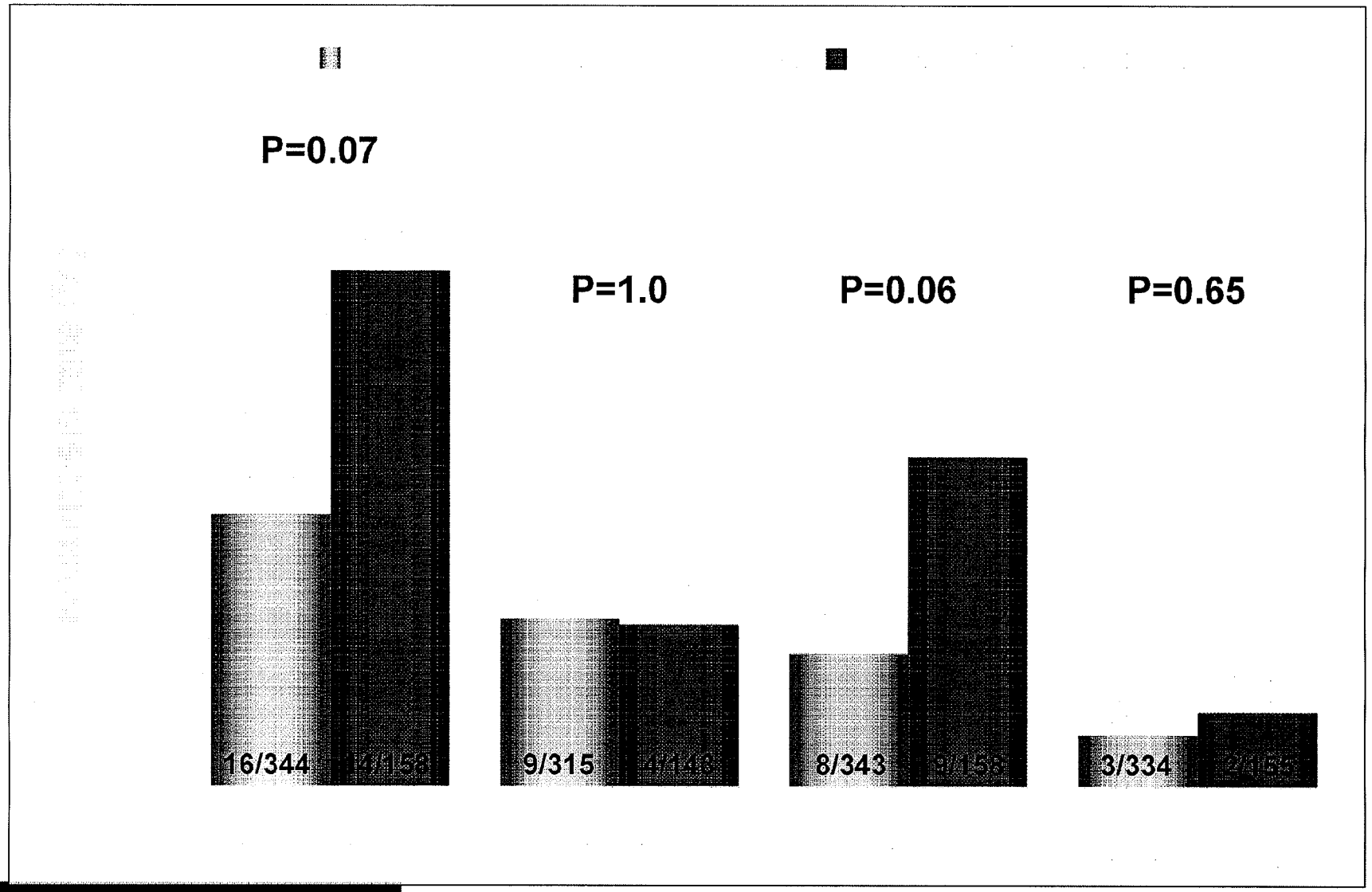
Binary Restenosis at 8 Months*



[redacted]

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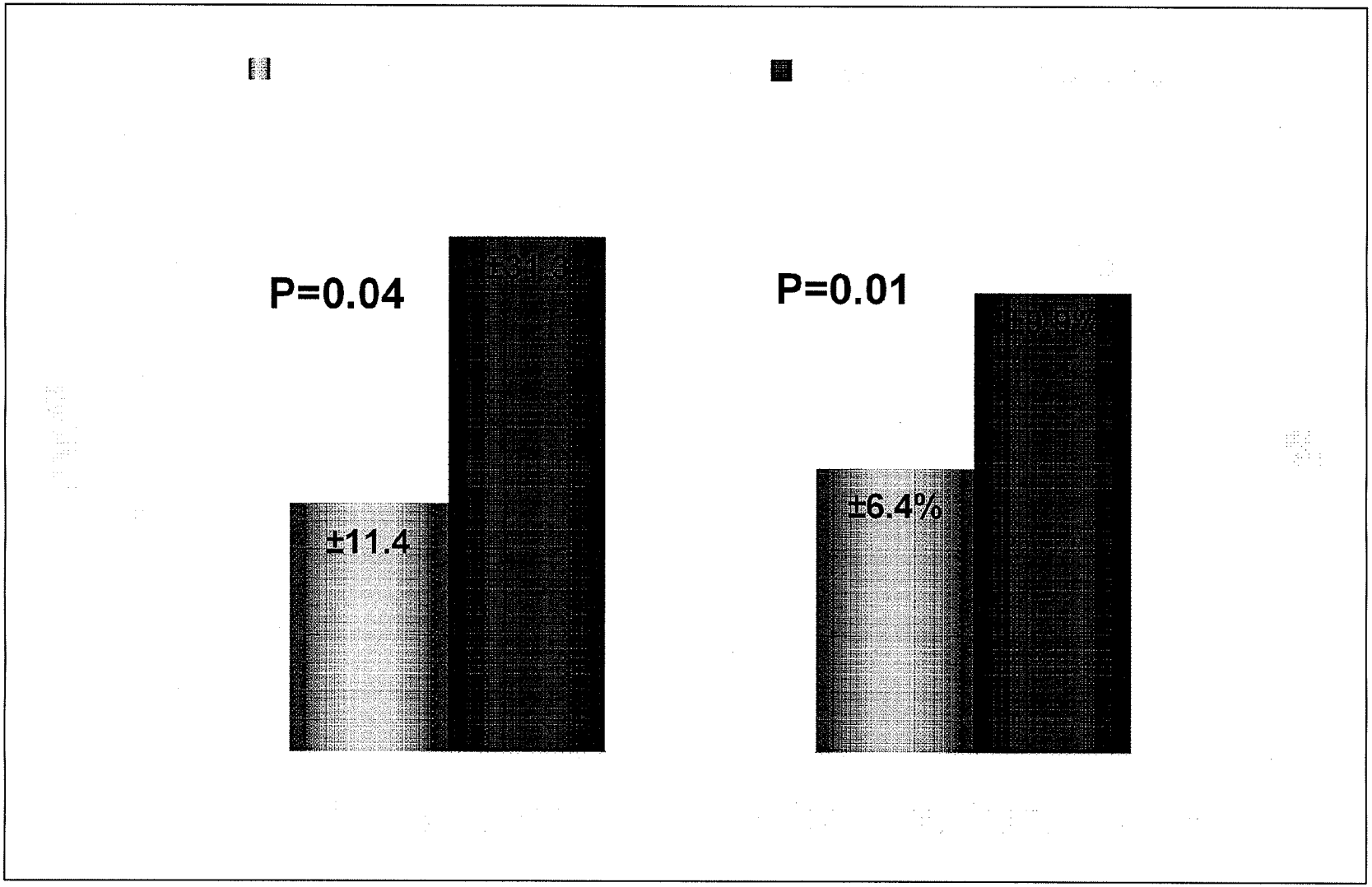
IVUS In-stent Measures at 8 Months*



[redacted]

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IVUS Incomplete Apposition
(Paired serial analysis)

	XIENCE V 90 lesions	TAXUS 43 lesions	P value
Post procedure	34.4%	25.6%	0.33
8 months	25.6%	16.3%	0.27
Resolved	8.9%	9.3%	1.0
Persisting	24.4%	14.0%	0.18
Late acquired	1.1%	2.3%	0.54

[redacted] stent thrombosis, showing
post procedure or at FU

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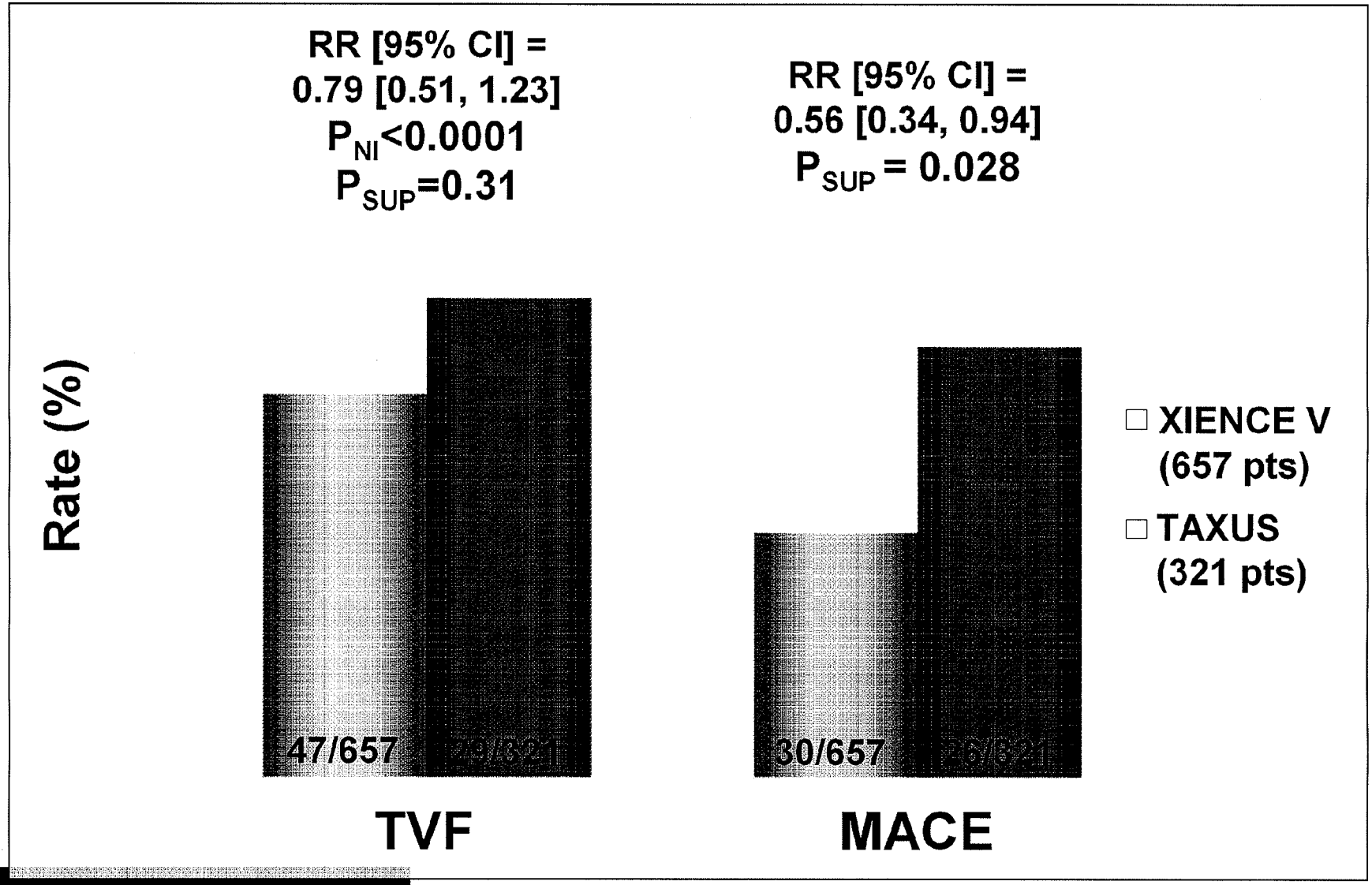
TVF and MACE Through 270 Days*



[redacted]ardiac death, MI, ischemia-driven TVR.
[redacted]emia-driven TLR.

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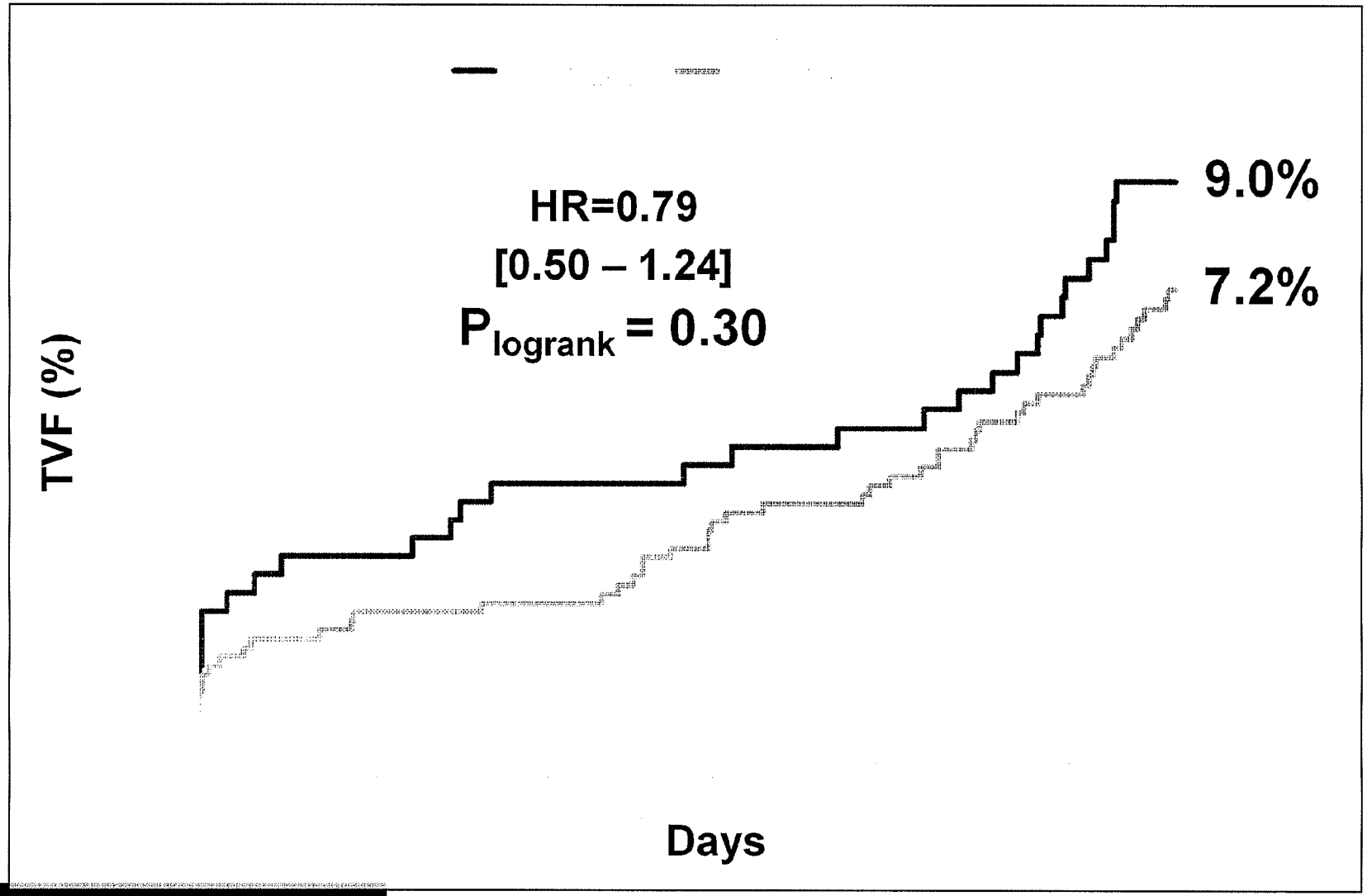
TVF Through 284 Days



[redacted]

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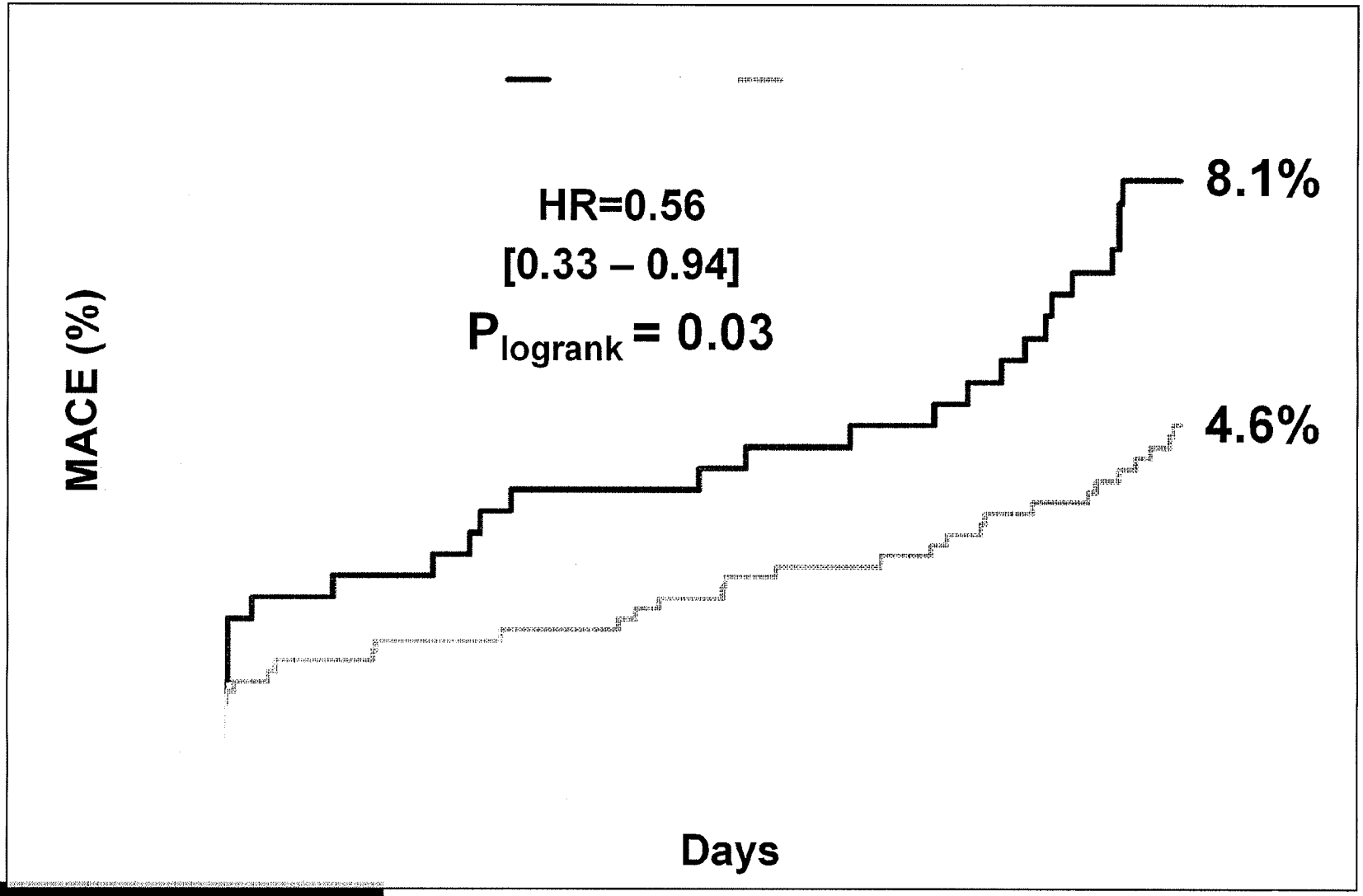
MACE Through 284 Days



[redacted]

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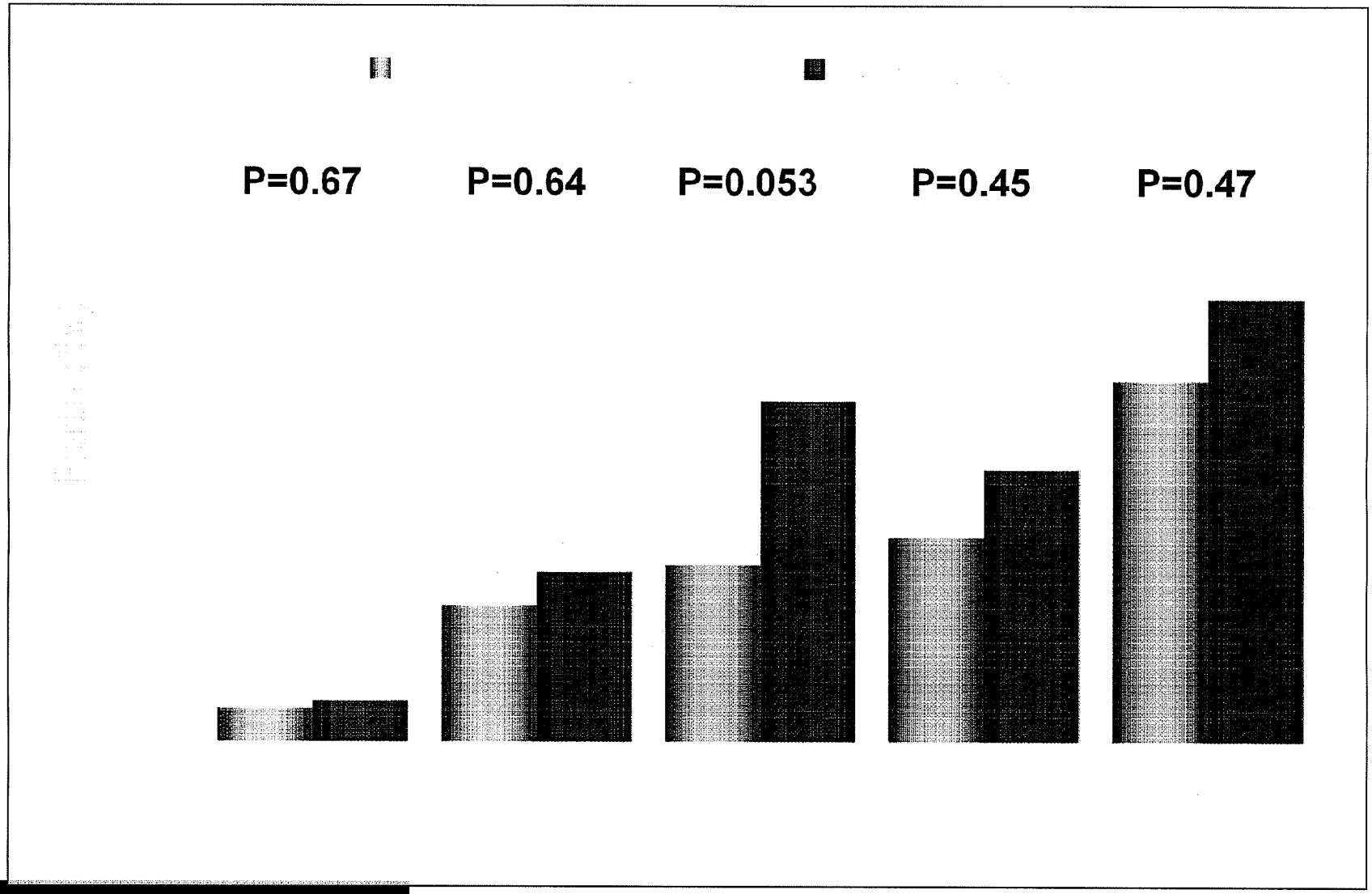
TVF Components Through 270 Days*



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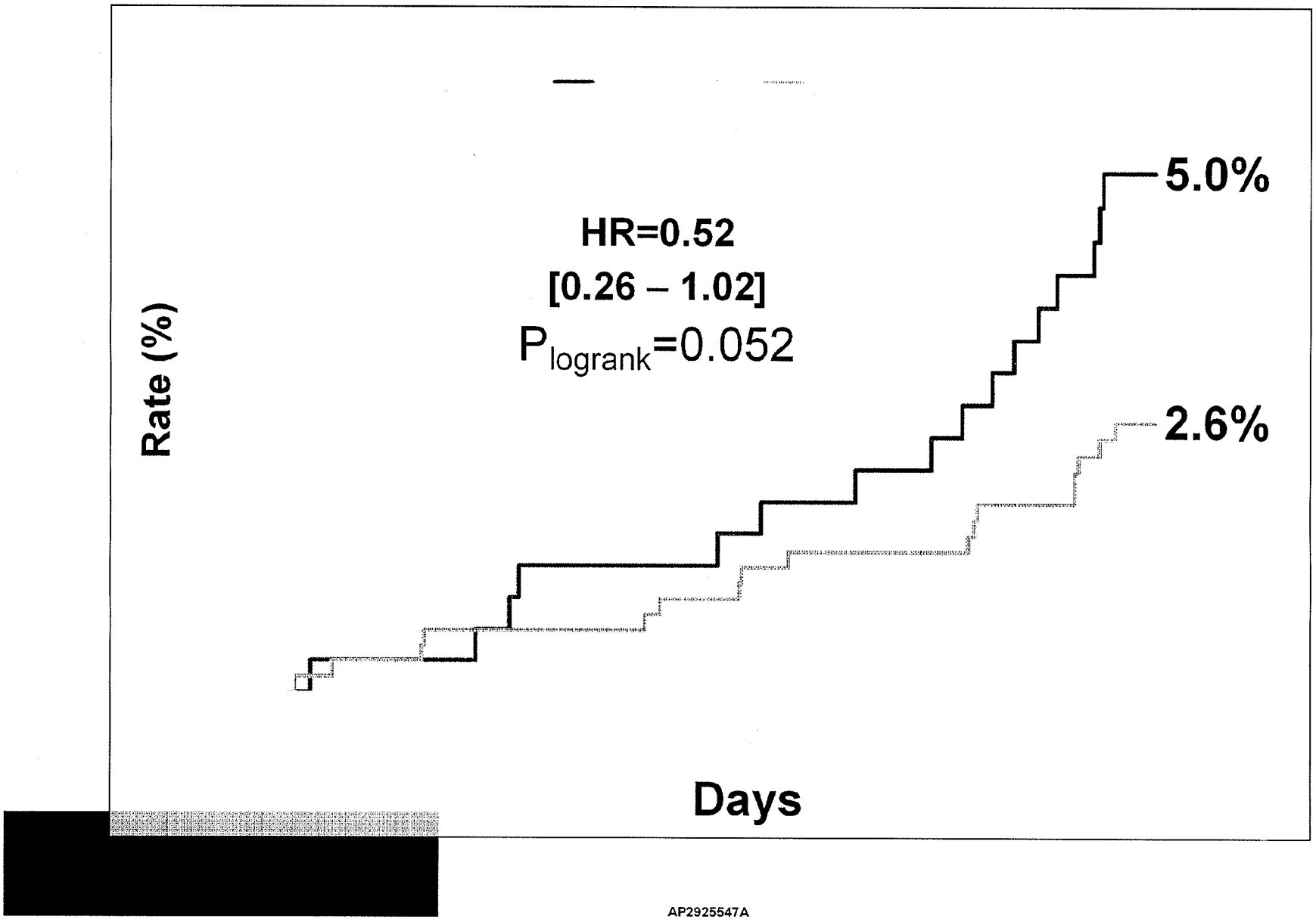
Ischemia-driven TLR Through 284 Days



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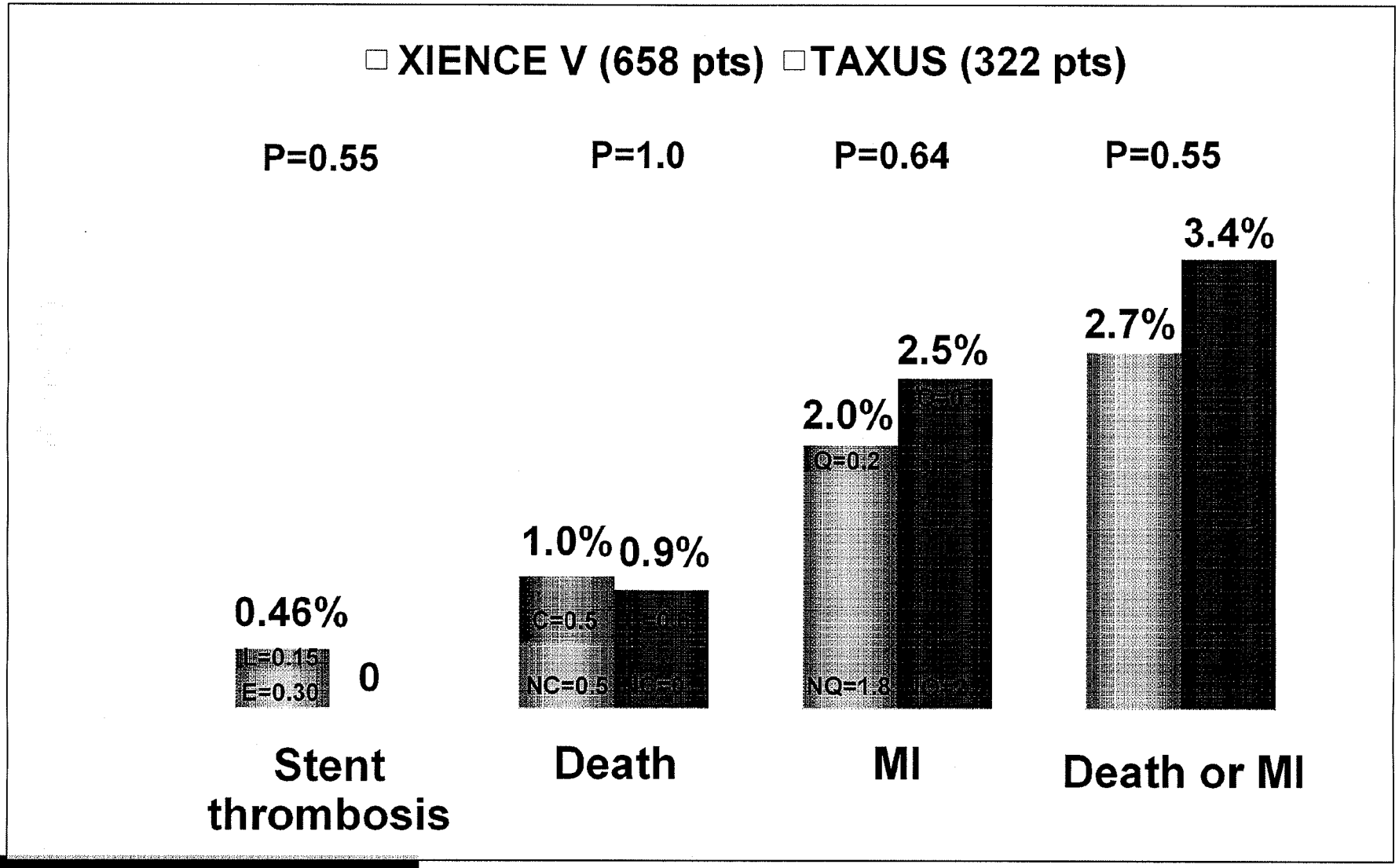
Safety Endpoints at 270 Days*



[redacted] (≤30d); L = late (>30d-9mo);
Q = Q-wave; NQ = non Q-wave

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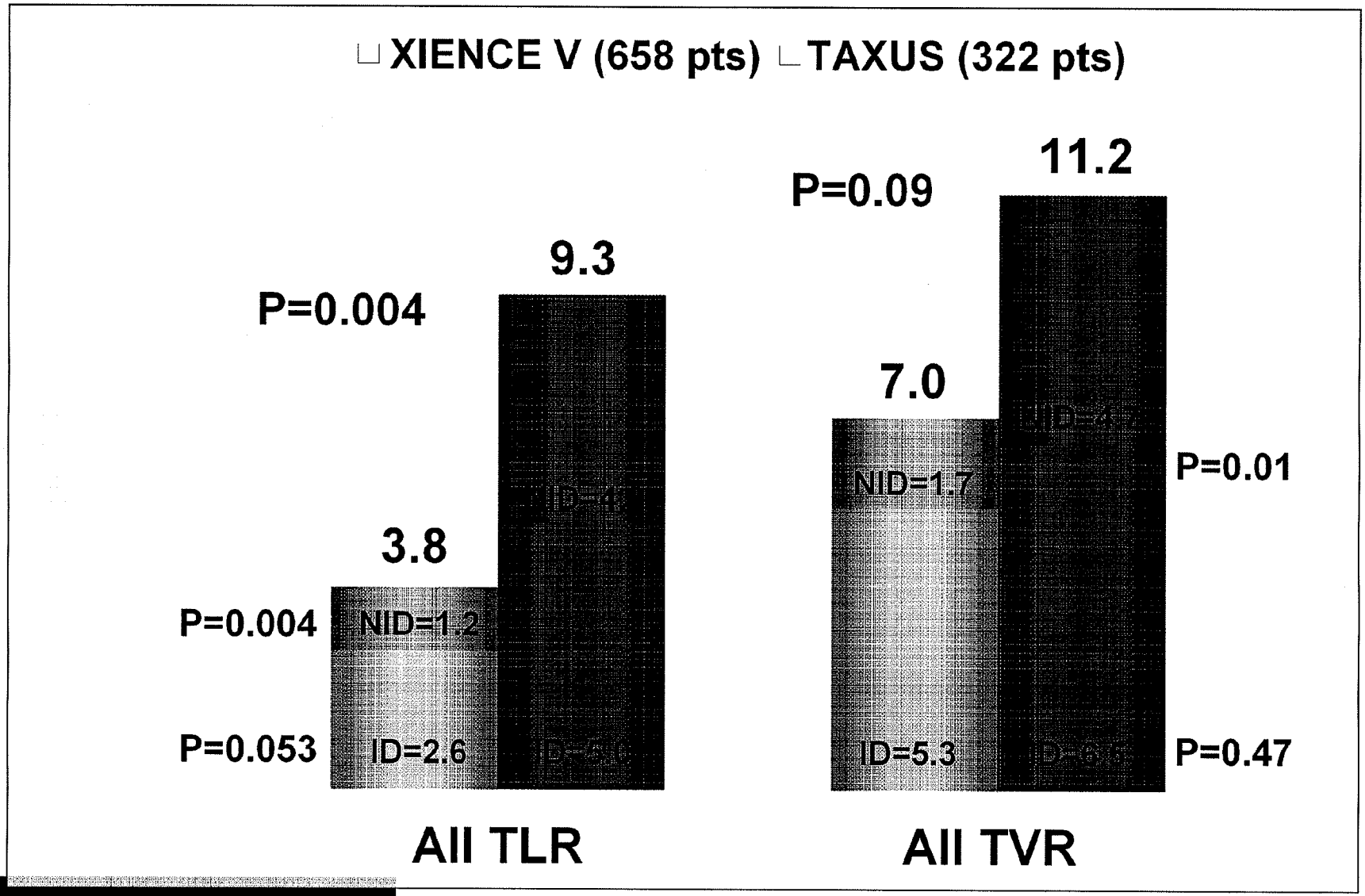
ABT1098609

Cordis et al. v. Abbott et al.
C.A. Nos. 07-2265, -2477, -2728, -5636 (D. N.J.)

A1341

All Revascularization Through 270 Days*



[redacted]emia-driven; NID=non ischemia-driven

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Conclusions I

- **In the large, multicenter, randomized SPIRIT III trial, the Everolimus Eluting XIENCE V stent compared to the paclitaxel-eluting TAXUS stent:**
  - **Was both non-inferior and superior in reducing in-segment late loss, the primary endpoint of the trial**
  - **Significantly reduced in-stent late loss at 8 months**
  - **Reduced angiographic FU diameter stenosis with a strong trend toward lower binary restenosis**
  - **Resulted in a significant reduction in in-stent volume obstruction without excess late acquired malapposition**

[redacted]

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Conclusions II

- In the large, multicenter, randomized SPIRIT III trial, the Everolimus Eluting XIENCE V stent compared to the paclitaxel-eluting TAXUS stent:
  - Demonstrated non-inferior rates of TVF at 9 months, with a significant 44% reduction in MACE
  - Showed a strong trend toward reduced ischemia-driven TLR, with a significant reduction in any TLR
  - Had similar rates of death, MI and stent thrombosis
- The primary and major secondary endpoints of the SPIRIT III trial were met

[redacted]

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